

Counterfeit Medicine In America: 2018

9th Annual Drug Abuse Symposium

October 29, 2018

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[Pharmaceutical Industry Labor-Management Association \(PILMA\)](#)

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[Spina Bifida Association of America](#)

[Texas Pharmacy Association](#)

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[Virginia Pharmacists Association](#)

[Vermont Pharmacists Association](#)

[West Virginia Rx](#)

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The Partnership for Safe Medicines

Americans are largely unaware of this threat. PSM awareness tools:

- ☐ Comprehensive reporting on counterfeit incidents online
- ☐ Explaining the risks in a variety of mediums
- ☐ Telling the stories of people who have been hurt by fake medicine



Closed Secure Drug Supply



Unregulated Foreign Drug Supply



The United States has
the safest drug supply in
the world...

...but as many as 19
million Americans buy
medicines outside that
supply chain, from foreign
online pharmacies or
other unlicensed sources.



The first wave of counterfeit medicines

"Basically, all my competition started selling drugs they were sourcing overseas from, in my opinion, unsafe countries and marketing them as Canadian. I couldn't compete with that," he said. (CBC 6/20/2017)

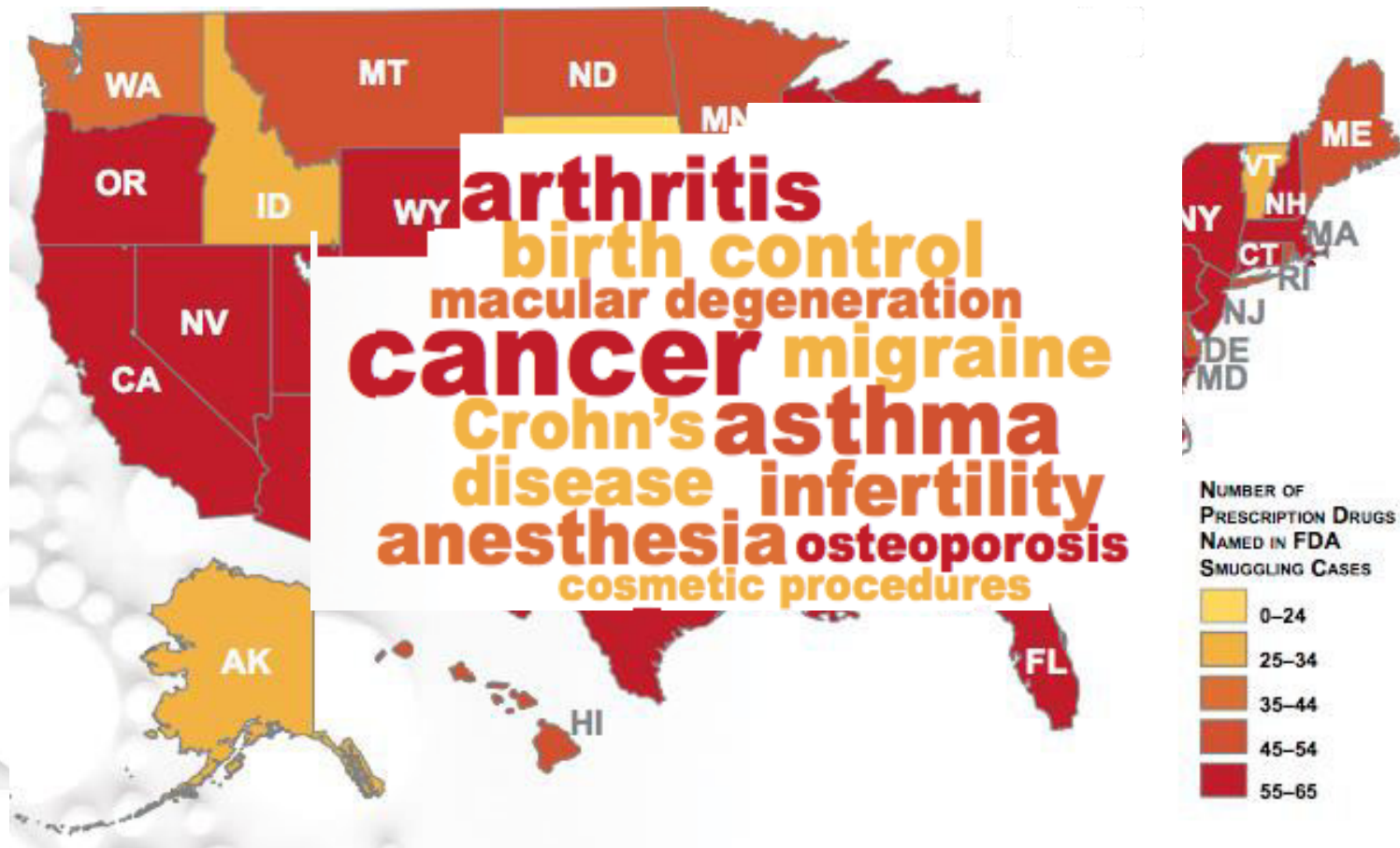
Canada's drug supply would be drained in 201 days, should just 20% of U.S. prescriptions shift to dispensing out of Canada.

(*Shepherd, Health Econ Outcome Res Open Access 2018, 4:1*)



Daren Jorgensen opened one of the first Canadian Internet fake pharmacies in 2001, and exited in 2008.

Since 2012, smugglers caught selling fake drugs sold up to 63 medications to over 3,000 doctors, clinics and hospitals across the U.S.



Counterfeit Avastin

In 2012, the FDA discovered 2 lots of an imported counterfeit cancer drug (Avastin) with **no active ingredient**.

The agency launched a massive recall and a lengthy investigation.

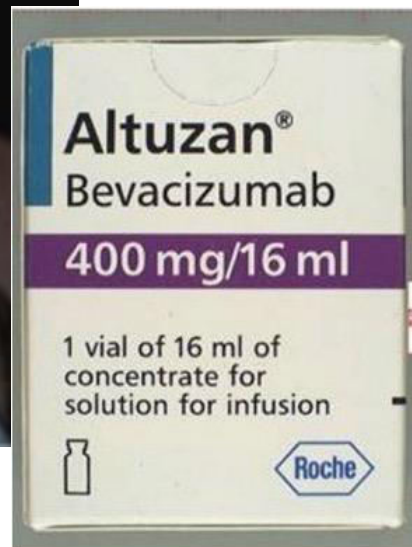


Public health threat is real

Late stage lung cancer Betty Hunter was treated with counterfeit Avastin in 2011. Ms. Hunter died three months later.



Source: Medicin der Dræber



Source: FDA

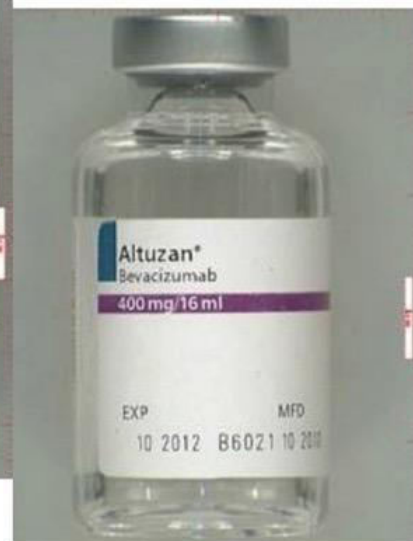
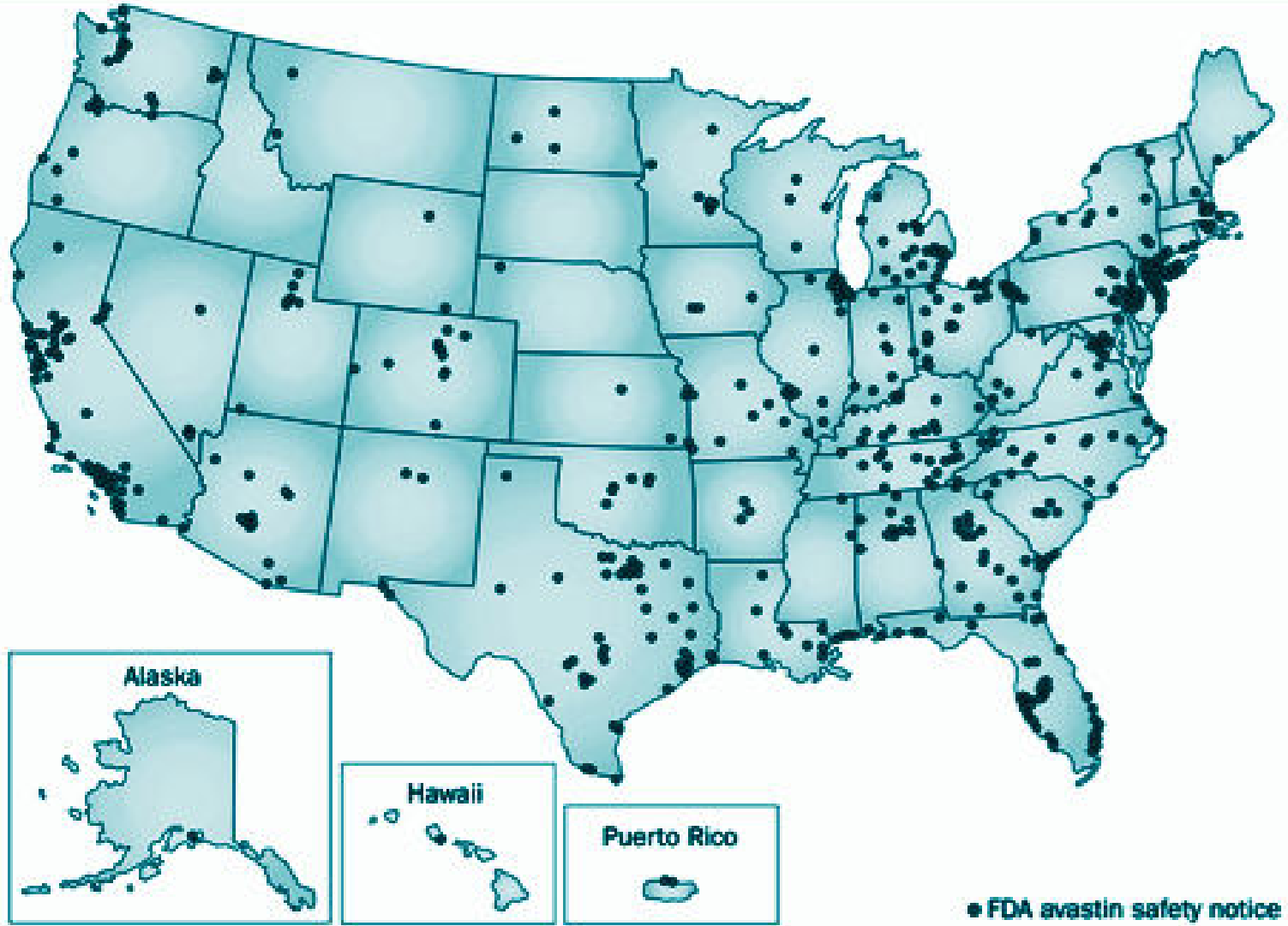


Figure 1: Visual depiction of a total of 949 FDA safety notifications that were sent to 932 physicians and/or clinics in 795 zip codes from 2012 to 2013.



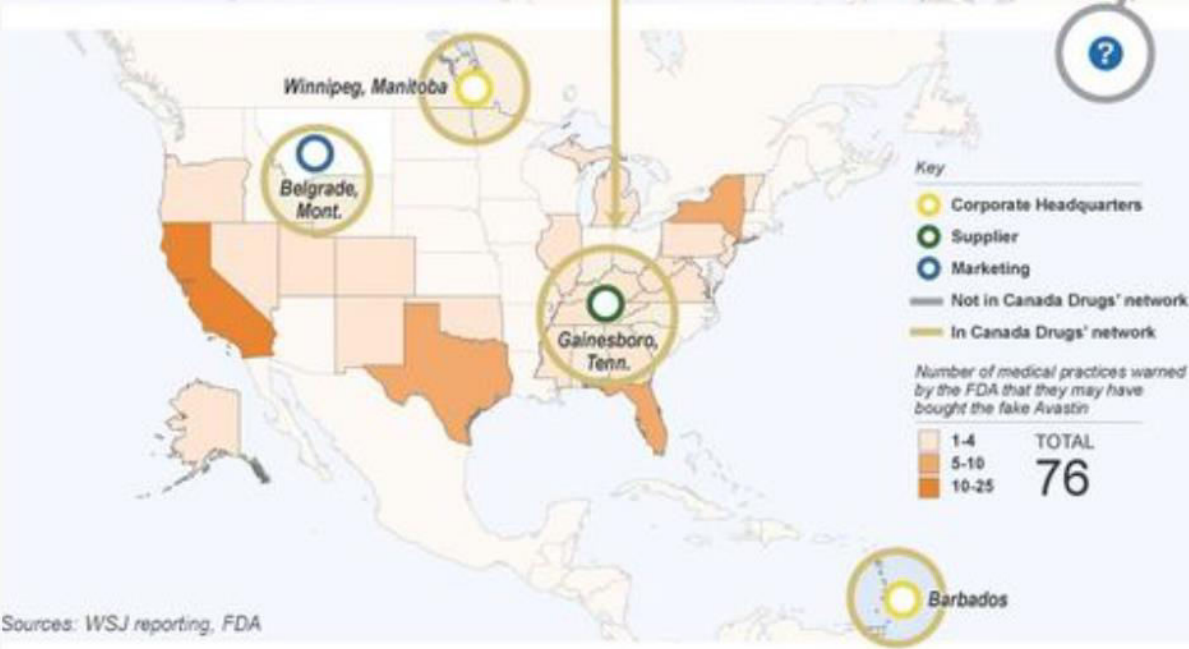
Case Study: Path of Fake Avastin

Path of Fake Avastin

The fake Avastin traveled through a series of overseas suppliers before reaching the Canada Drugs' network. Companies controlled by Canada Drugs procured the counterfeit cancer medicine, marketed it to U.S. doctors and shipped it through a contractor in Tennessee, court records and business documents show. Doctors identified by the FDA as the network's customers were warned that they may have bought the fake Avastin.

11

Select dots for more info



Graphic courtesy the Wall Street Journal

Lack of prosecution

Prosecuting foreign nationals for selling counterfeit drugs is hard, which makes a poor deterrent.

2014: DOJ indicted 5 CanadaDrugs.com executives for selling \$78 million of fake cancer drugs

2017: Canada set extradition hearing for May 2018.

2018: Plea approved - no jail time (\$34mm penalty)

2018: CanadaDrugs.com shut down, but license was transferred



The criminals - Where are they now?

Internet pharmacy pioneer's licence reinstated, just days after it was suspended

Kris Thorkelson's Manitoba licence was pulled on same day his Canada Drugs reached tentative plea deal in U.S.

By Karen Pauls, CBC News | Posted: Dec 21, 2017 5:03 PM CT | Last Updated: Dec 21, 2017 5:14 PM CT



American prosecutors accuse CanadaDrugs.com, its CEO Kris Thorkelson, affiliated companies and associates of selling \$78 U.S. in unapproved and counterfeit cancer drugs to U.S. doctors. (CBC)

Thorkelson's company, CanadaDrugs, continues to hold provincial wholesale pharmacy licenses and a Canadian Federal manufacturing pharmacy license.

Terms of **pending** plea deal with U.S. Department of Justice for Kris Thorkelson

- Six months house arrest and four and a half years of probation;
- a \$250,100 fine; and
- Turn over records and cooperate in future investigations.

The plea agreement does not require him to:

- serve any jail time;
- surrender his pharmacy license;
- enter a guilty plea of selling counterfeit drugs.

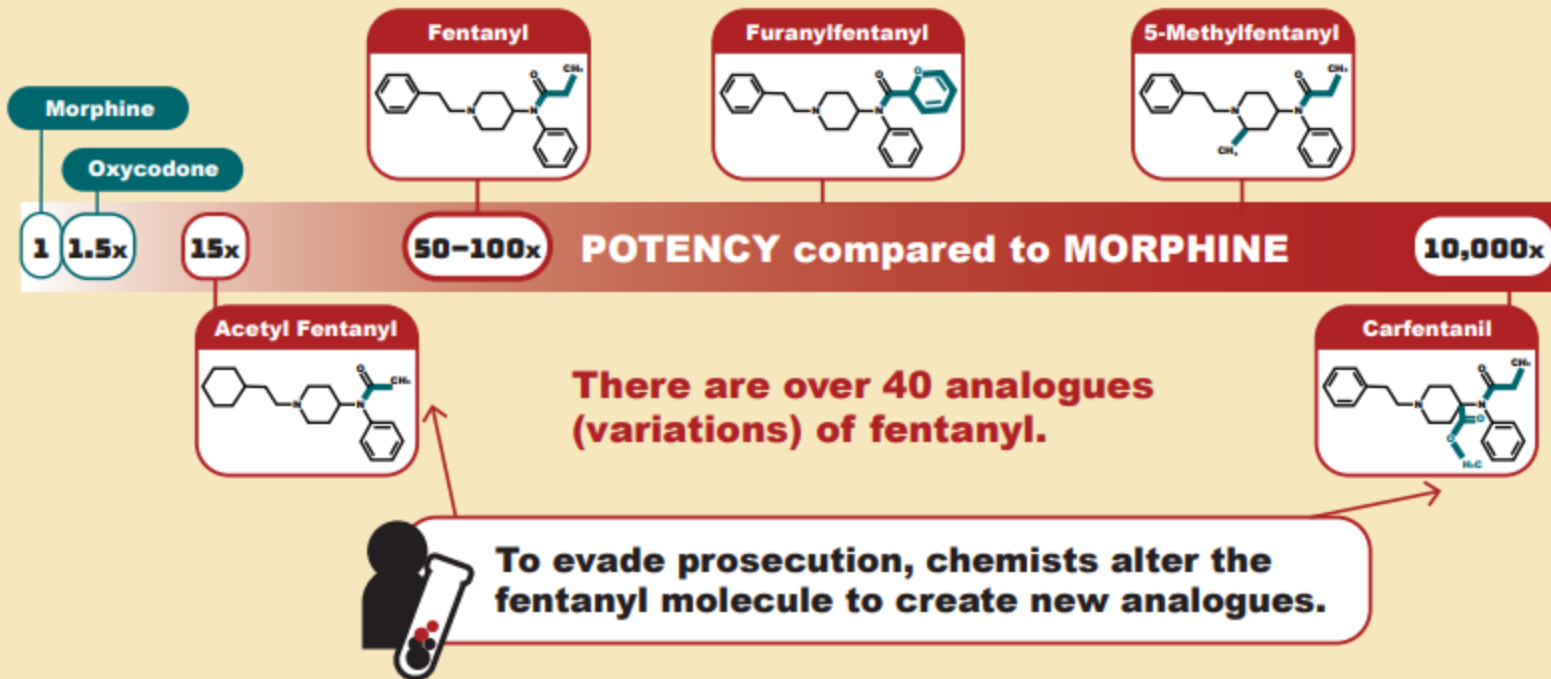
He is not prohibited from holding any kind of pharmacy license or starting a new pharmacy business to export to America.

FENTANYL 101

An introduction to the Fentanyl crisis in the U.S.

What are fentanyl and fentanyl analogues?

Fentanyl is a synthetic opioid that is 50–100 times more potent than morphine. Doctors prescribe fentanyl in medical settings, but drug traffickers manufacture black market fentanyl and sell it illegally.



Fentanyl-laced counterfeits



First reports of counterfeit Xanax and fake opioids laced with fentanyl and analogues in late 2015.

Fentanyl-laced counterfeits



Counterfeit Xanax

Source: Yakima Police Department



Counterfeit Oxycodone

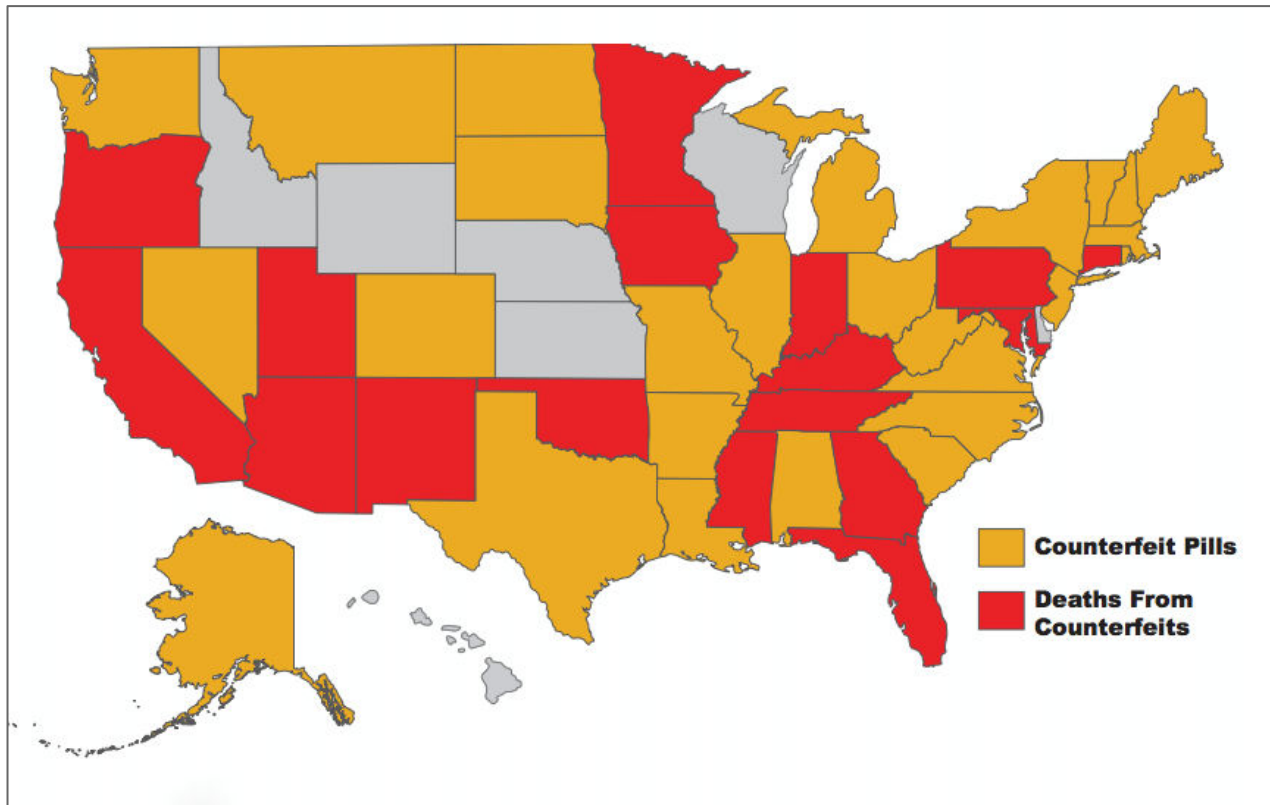
Source: Public Health Seattle & King County



Counterfeit Percocet

Source: Georgia Bureau of Investigations

Fentanyl-laced counterfeit



Pills have been found in 43 states, with deaths reported in 22 – March 2018

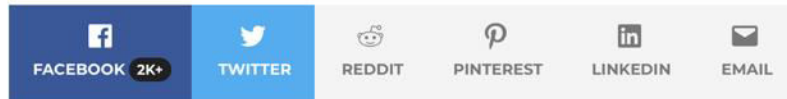
Full report: “Forty Three States and Counting” at www.safemedicines.org

Select fentanyl-laced counterfeit seizures



Police say residence in Utah was home to one of the largest fentanyl operations in the U.S.

POSTED 9:27 PM, MAY 31, 2017, BY KIERSTEN NUÑEZ, UPDATED AT 07:03AM, JUNE 1, 2017



This is an archived article and the information in the article may be outdated. Please look at the time stamp on the story to see when it was last updated.



20,000 fentanyl pills seized at border in San Diego, beating record set last week



HEROIN

3 Summit County men indicted in large seizure of fentanyl pills

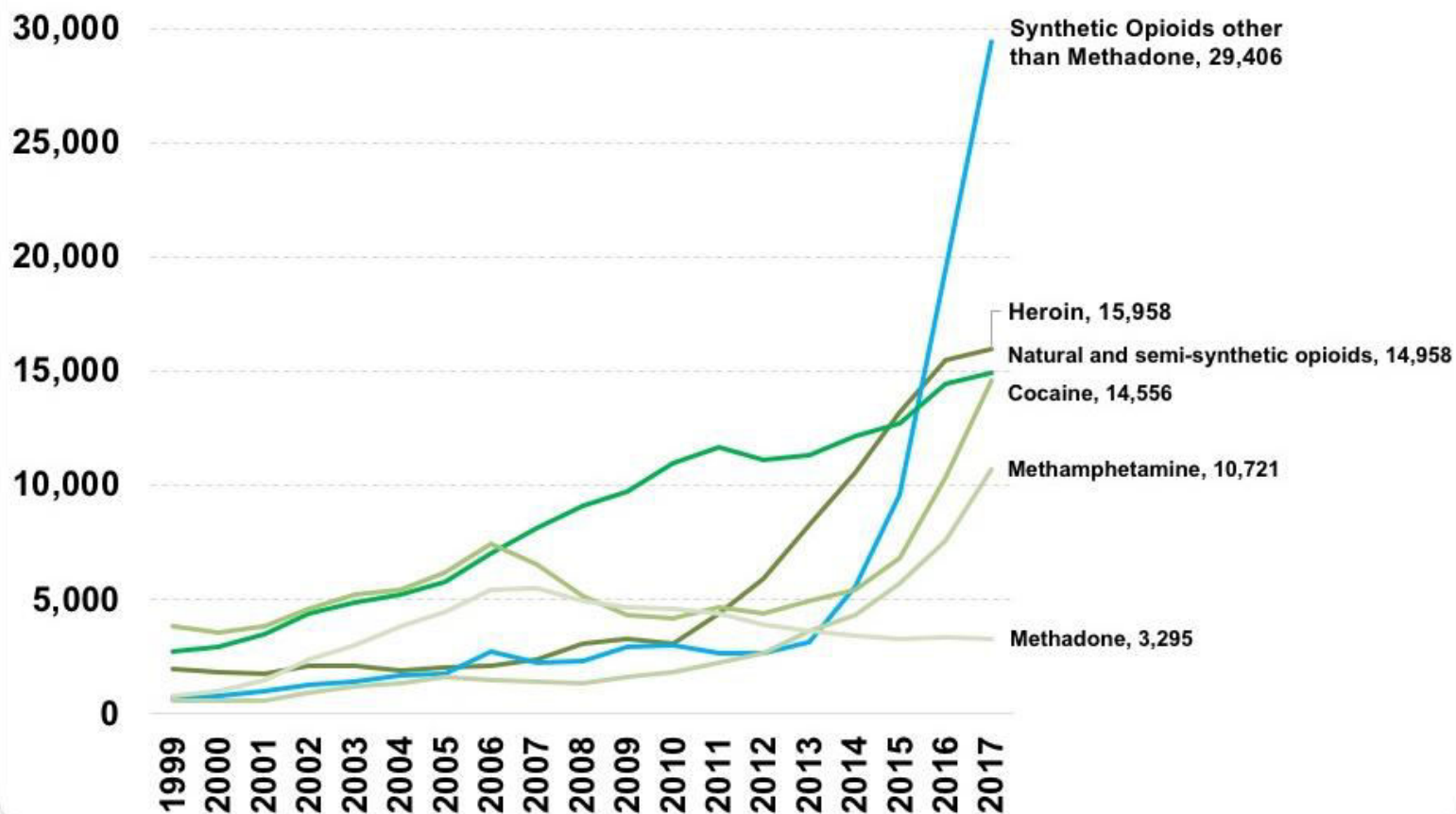
U.S. Attorney Justin Herdman believes the arrests helped save at least 1,500 lives.

Author: Associated Press
Published: 6:40 PM EDT May 3, 2018
Updated: 6:44 PM EDT May 3, 2018

CLEVELAND (AP) - Federal prosecutors say three Summit County men have been indicted in a seizure of 1,500 fentanyl pills marked as the less potent opioid oxycodone.

Fentanyl is driving overdose deaths

Drugs Involved in U.S. Overdose Deaths, 1999 to 2017



Data source 1999-2017: [CDC](#)
searchable database [CDC Wonder](#).

Fentanyl-laced counterfeits in Indiana

The Journal Gazette
April 30, 2018
Local News Sports Business Live

JGFRANK GRAY



Police warn of pills designed to look like Xanax

Sunday, April 10, 2016 4:06 am

Fake pills bringing r to youths

Frank Gray

Two years ago, Fort Wayne Police Capt. Kevin Hunter attended where participants were warned that "if you think synthetic s benzodiazepine arrives."

The prediction has arrived, in the form of fake Xanax.

It has appeared all over the country, and it's leaving a trail of

UNCL

Fake Rx in Indian Fentanyl found Oxycod

This DEA Bulletin is based on preliminary reporting and becomes available.

DEA-CHI-BUL-167-17
AUGUST 2017

Event

A recent enforcement operation by the (DEA) Indianapolis District Office (IDO) prescription pills that were various sha oxycodone. Laboratory analysis subse counterfeit; the dark blue pills containe contained fentanyl. Fentanyl is a Sche 50 to 100 times more potent than morp substance, similar in structure to fentar times that of morphine and is used in v large animals, including elephants. Bo

Significance

Based on information from the Indiana (IMPD), this is the first time carfentanil crime laboratory. The presence of carf safety issue for law enforcement offica toxicity. Carfentanil and fentanyl press pills also present a serious safety issue purchasing these pills as they may not carfentanil and/or fentanyl. The ingest highly potent drugs could result in a ra throughout the Indianapolis area. At th overdoses related to these particular c

Details

In May 2017, an IDO enforcement ope felons and the seizure of approximately heroin and methamphetamine; 1 pound stolen vehicle. This investigation was i

UNCLASSIFIED


≡ TribuneStar

BREAKING TOPICAL FEATURED

THPD: Counterfeit oxycodone pills could prove fatal

Pills may be laced with potent and possibly deadly fentanyl

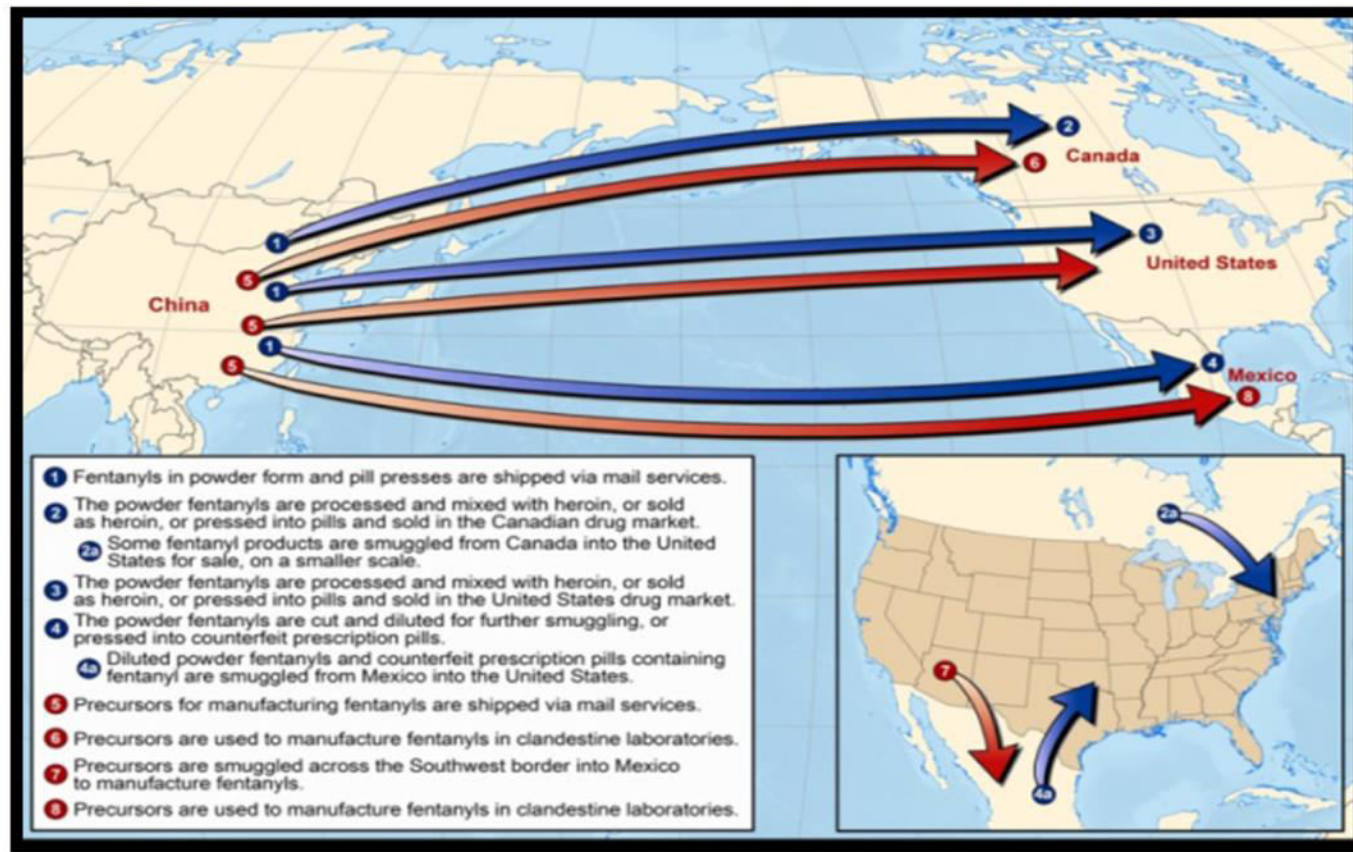
Tribune-Star staff report Jun 1, 2018



Associated Press

This undated photo provided by the Cuyahoga County, Ohio, Medical Examiner's Office shows fentanyl pills made to look like the less-potent opiate oxycodone. This batch was seized in Cleveland, Ohio. Terre Haute police say similar pills now are entering west central Indiana. Police and health officials are warning of the danger of fatal overdose.

All fentanyl is imported



Since 2015, counterfeit pills that are laced with deadly imported fentanyl have been killing Americans across the U.S.

Fentanyl is cheap and readily available online

Investigators for the US Permanent Subcommittee of Investigations communicated with online vendors who sold fentanyl. They provided the following price list to the investigators.

A kilo of fentanyl costs roughly \$11,000 when paid through Western Union. A fatal dose of fentanyl for an adult is as little as 2-3mg.

That's enough for 333,333 fatal doses.

Read the entire report: [Combating the Opioid Crisis: Exploiting Vulnerabilities In International Mail, Staff Report, Permanent Subcommittee on Investigations, US Senate.](#)

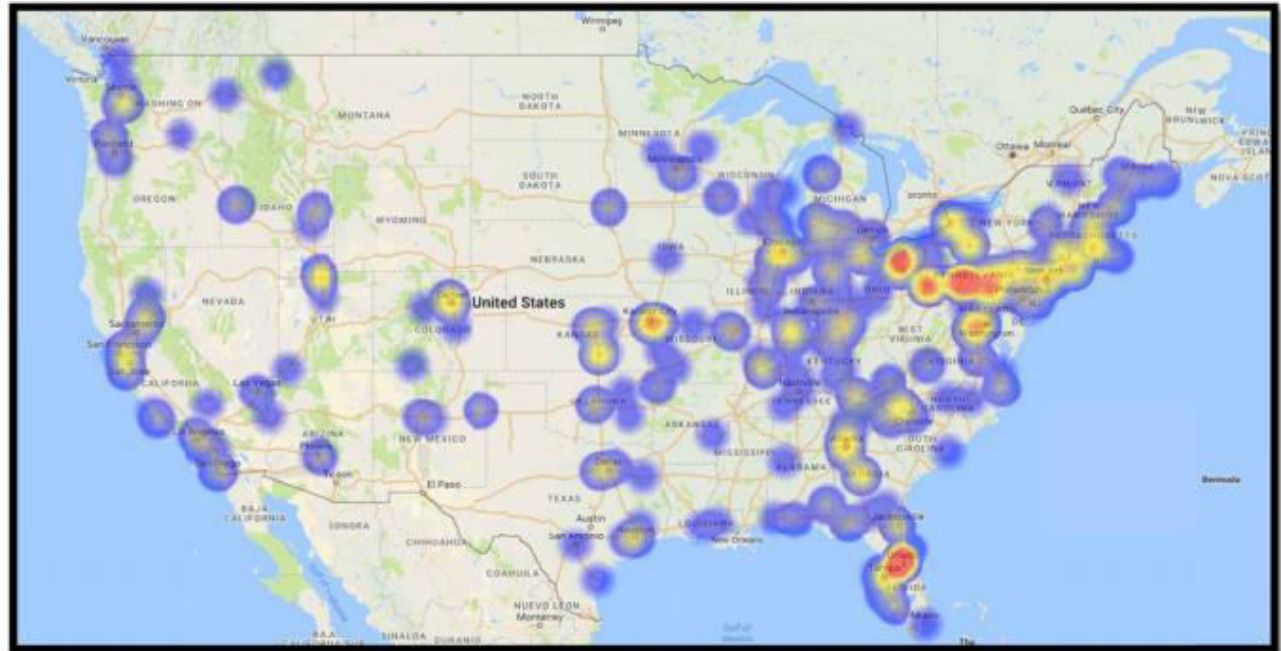
From: [REDACTED]
To: [REDACTED]
Date: Thu, Jun 15, 2017 at 3:27 AM
Subject: Re: Research Chemicals For Sale USA Contact: Order Help

Weight	Western Union+ incl. Reship gurantee	Bitcoin + incl. Reship guarantee	Western Union - no Reship	Bitcoin -no Reship
2g	145\$	133\$	78\$	71\$
10g	232\$	213\$	143\$	131\$
25g	394\$	362\$	265\$	243\$
50g	665\$	611\$	467\$	429\$
100g	1206\$	1109\$	873\$	803\$
250g	2829\$	2602\$	2091\$	1923\$
500g	5535\$	5092\$	4120\$	3815\$
1000g	10949\$	10073\$	7573\$	7524\$

Law enforcement and journalists working on this issue report fentanyl for sale for \$3.5k-\$5k/kg.

Fentanyl is cheap and readily available online

During the committee's investigation, they tracked five sellers in China for a short time period. During the time of that investigation, they tracked their sales and shipments to purchasers in 43 different states.



Read the entire report: [Combatting the Opioid Crisis: Exploiting Vulnerabilities In International Mail, Staff Report, Permanent Subcommittee on Investigations, US Senate.](#)

How does it get here?



Scott Gottlieb, M.D. 
@SGottliebFDA

Follow

Toured operations at [#FDA](#) JFK Airport mail facility. Just some of thousands of seized fake, controlled drug packages



9:33 AM - 25 Aug 2017

Source: Twitter

“..many Americans are purchasing fentanyl and other illicit opioids online and having them shipped here through the international mail system.” Jan. 23, 2018

COMBATTING THE OPIOID CRISIS:
EXPLOITING VULNERABILITIES
IN INTERNATIONAL MAIL

STAFF REPORT

PERMANENT SUBCOMMITTEE ON
INVESTIGATIONS

UNITED STATES SENATE



Die molds are readily available for any kind of pill

The TDP die molds Xanax for tablet press pill press die pill machine TDP-0/1.5
Sold by Q121402663
★★★★★ 1 Review(s) | 3 Transactions

Free Shipping

Store No: 1755750

Price: **US \$151.08 - 171.8** / Piece Reference Currency ▼

Wholesale Price (Piece):	1 +	2 +	7 +
	US \$171.80	US \$156.59	US \$151.08

Quantity: Piece



days ?

Fentanyl to counterfeit pill

AliExpress

I'm shopping for...

New here? Get your coupons!

Store: Donna grocery store 95.6% Positive feedback Follow

Home > All Categories > Tools > Power Tools > Grinders

Single punch tablet press machine TDP-1.5 pill press machine / pill making / TABLET PRESSING, pill making

★★★★★ 5.0 (1 votes) 4 orders

Price: US \$786.00 / piece
Discount Price: **US \$746.70** / piece -5%
03h:57m:26s
Get our app to see exclusive prices

Shipping: US \$368.42 to United States via Seller's Shipping Method
Estimated Delivery Time: 20-38 days

Quantity: - 1 + piece (987 pieces available)

Total Price: US \$1,115.12

Buy Now Add to Cart

Add to Wish List (33 Adds) Recently Viewed



Xanax 2 Punching Die Stamp Mold for TDP-0/1.5 Pill Maker Machine

Price: **US \$119.6 - 136.0** / Piece

Wholesale Price (Piece):	1 +	3 +	9 +
	US \$136.00	US \$123.96	US \$119.60

Quantity: Piece

Shipping Cost: **Free Shipping** to United States Via ePacket

Estimated delivery time: Aug 27 and Sep 18, ships out within 24h

Total Cost: **US \$136.00**

2017: CBP LA seized 396 pill presses

Illegal molds exist for all pills

95,000 pills seized in Cottonwood, Utah - 2016



Aaron Shamo and 5 others allegedly manufactured and sold hundreds of thousands of fake prescription pills across the U.S. via the **Darknet**.

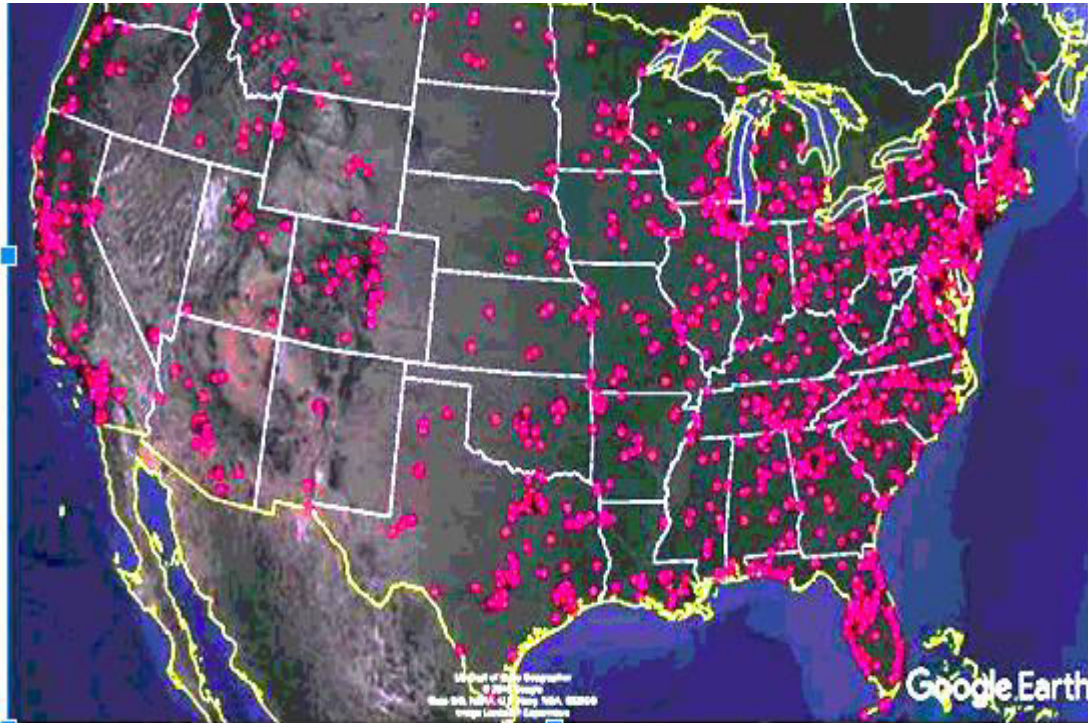
They used pill presses, dies, and stamps and illegally imported fentanyl and alprazolam from China.

In the November 2016 raid, the DEA seized \$1.2 million and 95,000 pills that could have been sold for as much as \$2.2 million. His trial is set for August 2018.



Source: www.deseretnews.com

Just one criminal ring can have a huge impact on the country



The Shamo ring out of Utah had many of their shipments traced to cities all over the country. This map shows where they sent pills after investigators finished combing through their sales records.

Locations That Shamo Drug Ring Shipped Pills
Source: U.S. Immigration and Customs Enforcement

Tosh Ackerman of Aptos, CA

The evening of October 27, 2015, 29-year-old Aptos, California resident Tosh Ackerman took a benadryl and part of a Xanax pill to help him sleep. He never woke up, and his girlfriend found him dead the next day.

Investigation showed that Ackerman's Xanax was counterfeit. It contained a fatal dose of fentanyl.

Carrie is an active speaker to schools and the media. You can reach her at ToshStory@gmail.com

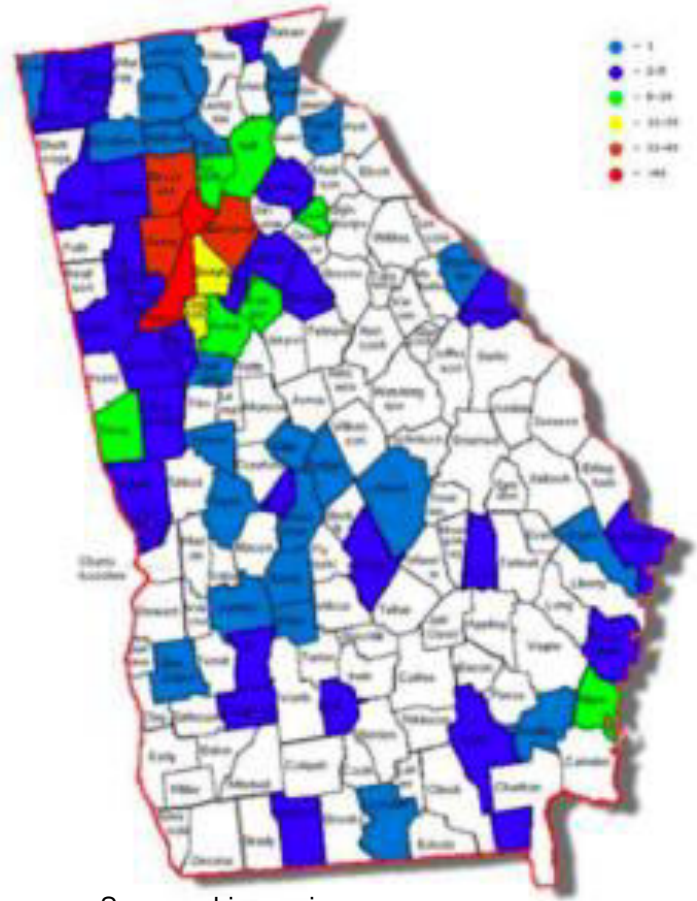


Betty Jean Collins of Macon, Georgia

A 60-year-old Macon resident recovering from open-heart surgery took one of her husband's Percocets and ended up in the hospital with an overdose. The medication was counterfeit—made with fentanyl—and Collins was one of a series of poisoning cases across Georgia.



Authorities warn of a deadly strain of counterfeit Percocet that looks like this with PERCOCET stamped at an angle and not as deeply as genuine medication. *Special to The Telegraph* - breaking@macon.com



Source: gbi.georgia.gov

Fentanyl trade attracts organized crime


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Suspected Mexico cartel leader charged with smuggling 44 pounds of fentanyl into the city

BY REUVEN BLAU FOLLOW
NEW YORK DAILY NEWS Updated: Wednesday, March 28, 2018, 1:03 AM



Francisco Quiroz-Zamora is charged with smuggling 44 pounds of fentanyl into the city. (DRUG ENFORCEMENT ADMINISTRATION/HANDOUT)

A high-level drug trafficker from Mexico was arrested and charged with smuggling more than 44 pounds of fentanyl into the city, authorities announced Tuesday.

Francisco Quiroz-Zamora, 41, a suspected leader of the powerful Sinaloa cartel, faces drug-trafficking conspiracy charges.

Major Bust Brings Down Drug Ring Selling Sinaloa Cartel Drugs – Including Fentanyl And Fentanyl Pills

October 19, 2018

The Deadly Counterfeit Drug Trade Thrives in California

San Francisco, March 2018: The counterfeit drug trade in California is a multi-billion dollar industry that has become a major public health and safety threat. The state's drug enforcement agencies are struggling to keep up with the demand for counterfeit drugs, which are often sold in large quantities and are highly addictive.

San Diego, March 2018: A major bust in San Diego has resulted in the seizure of thousands of counterfeit drugs, including fentanyl and fentanyl pills. The drugs were found in a warehouse and were being sold to a large number of customers.

San Jose, March 2018: A major bust in San Jose has resulted in the seizure of thousands of counterfeit drugs, including fentanyl and fentanyl pills. The drugs were found in a warehouse and were being sold to a large number of customers.

Opening the U.S.'s closed drug supply chain puts California users at risk of serious injury or death.

Click here to learn about other counterfeit drug incidents in California

The *Ventura County Star* reported on a press conference announcing the bust of a major drug trafficking ring operating in the area with ties to the Sinaloa cartel and the seizure of \$10.8 million worth of drugs. At the press conference, Ventura County Undersheriff Gary Pentis said it was the discovery of fentanyl pills that started this whole investigation: "Early on, one of the first seizures was fentanyl; bogus prescription counterfeits made with synthetic fentanyl to simulate the high of opiates." Those pills looked like Roxicodone pills.

On multiple tables behind the sheriff were all the drugs seized during this year-long operation: 285 pounds of methamphetamine, 121 pounds of cocaine, 13.2 pounds of heroin, 6.6 pounds of powdered fentanyl, and the 600 counterfeit Roxicodone. Pentis stated that the powdered fentanyl was seized in the city of Camarillo. For the Ventura County Sheriff's Office,

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NEWS OPINION SPORTS ENTERTAINMENT LIFESTYLE BUSINESS

CLASSIFIEDS Local Politics Columnists National U.S. Politics


Obituaries

BOSTON HERALD Morning Meeting with Hillary Chabot, Tom Shattuck

Expert: Sinaloa cartel moved to fentanyl to meet demand

Joe Dwinell Friday, February 09, 2018

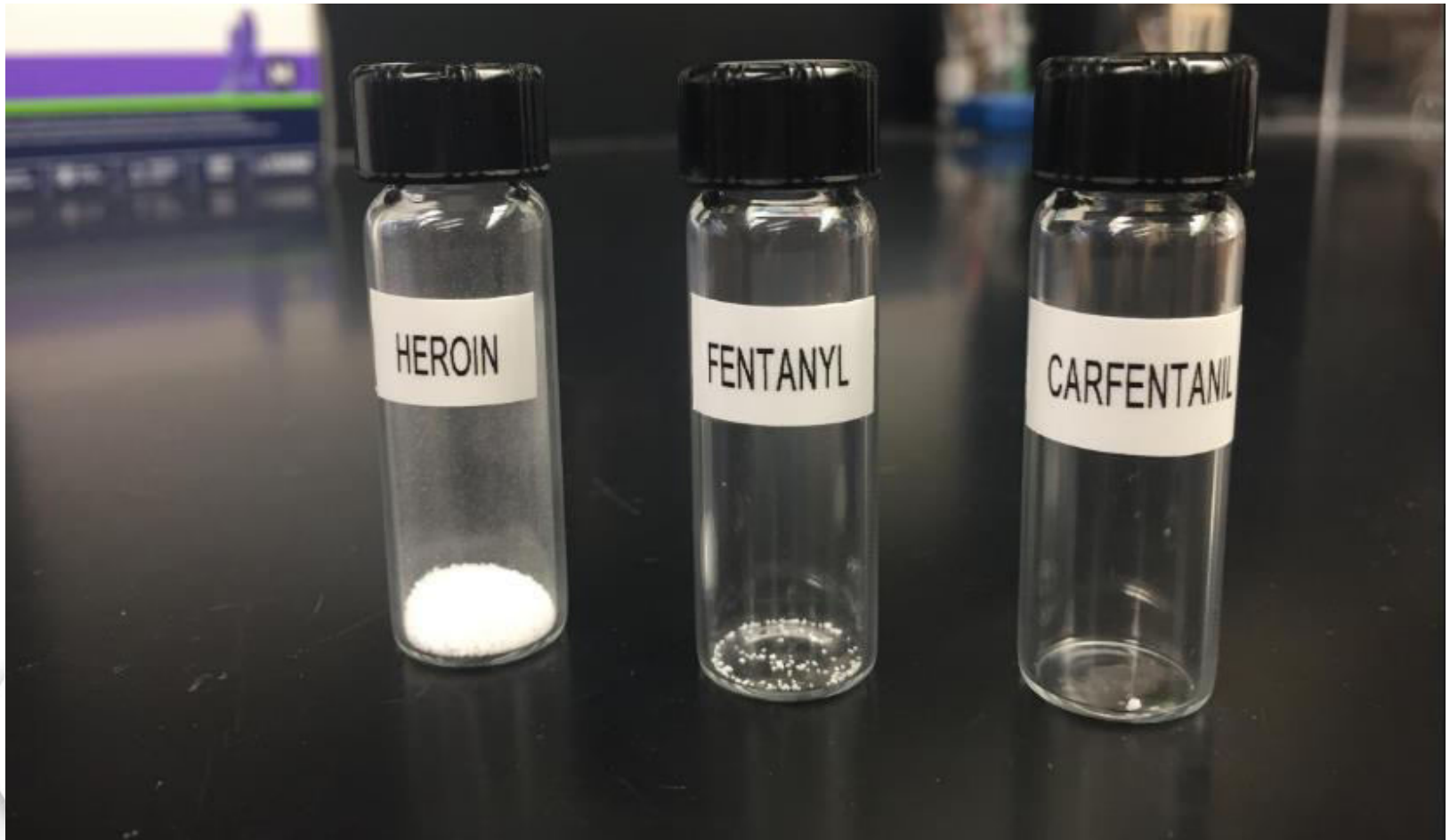
OPERATION HIGH HOPES



HEROIN/FENTANYL
FENTANYL PILLS
COCAINE
OXYCONTIN
CASH

Credit: Courtesy

What does a fatal dose look like



[Photo originally created by New Hampshire Public Radio photographer Paige Sutherland](#)

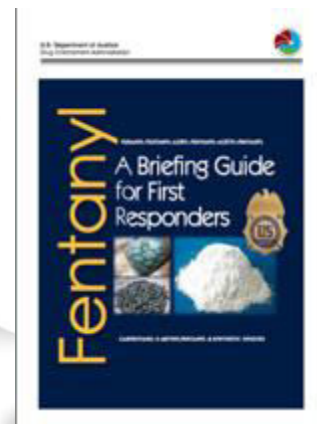
Law enforcement risk: officer exposure

- Minuscule (2-3mg) exposure can cause injury and death.

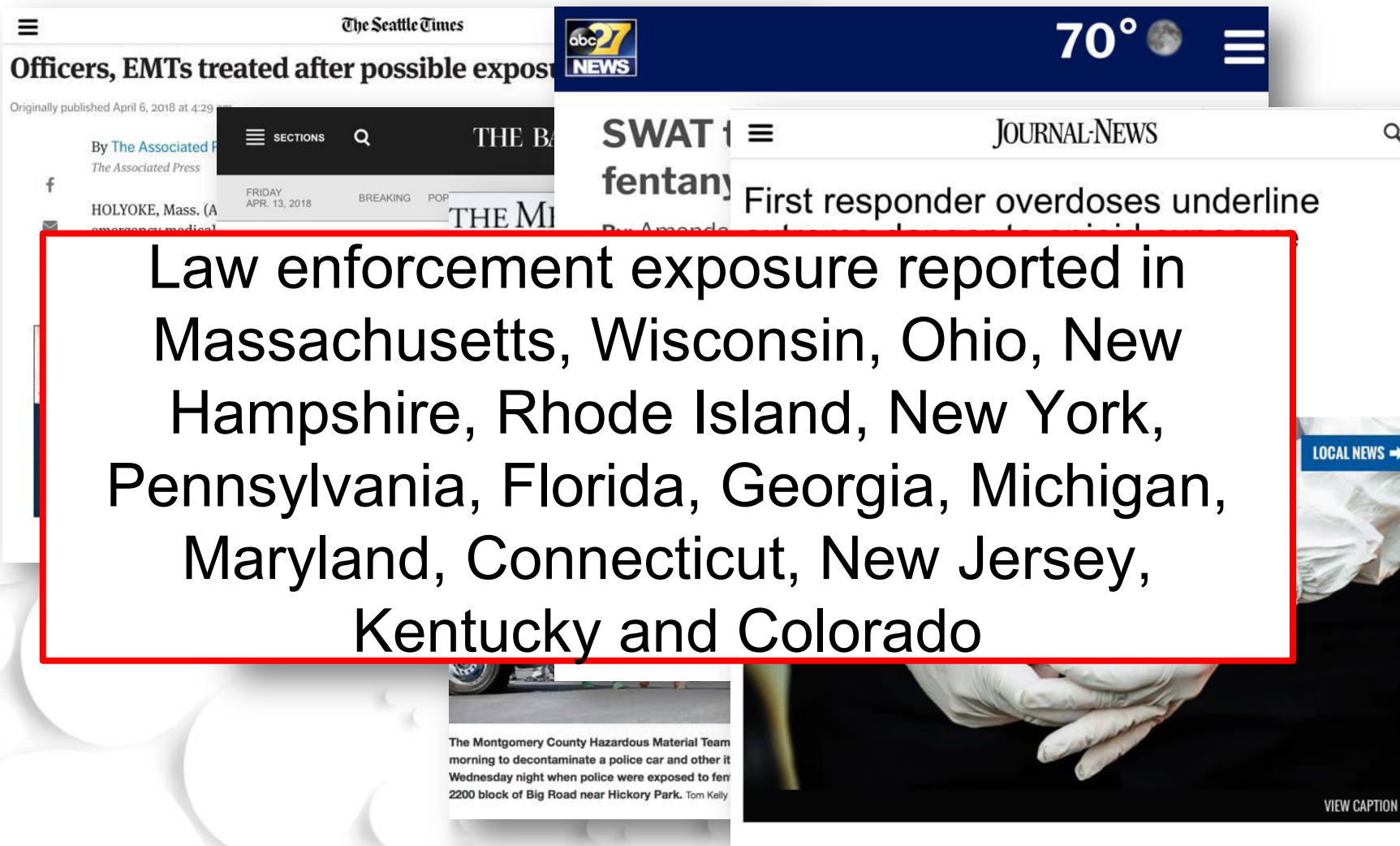


Source: KEPRTV.com

- New procedures for law enforcement
- Suspension of field tests

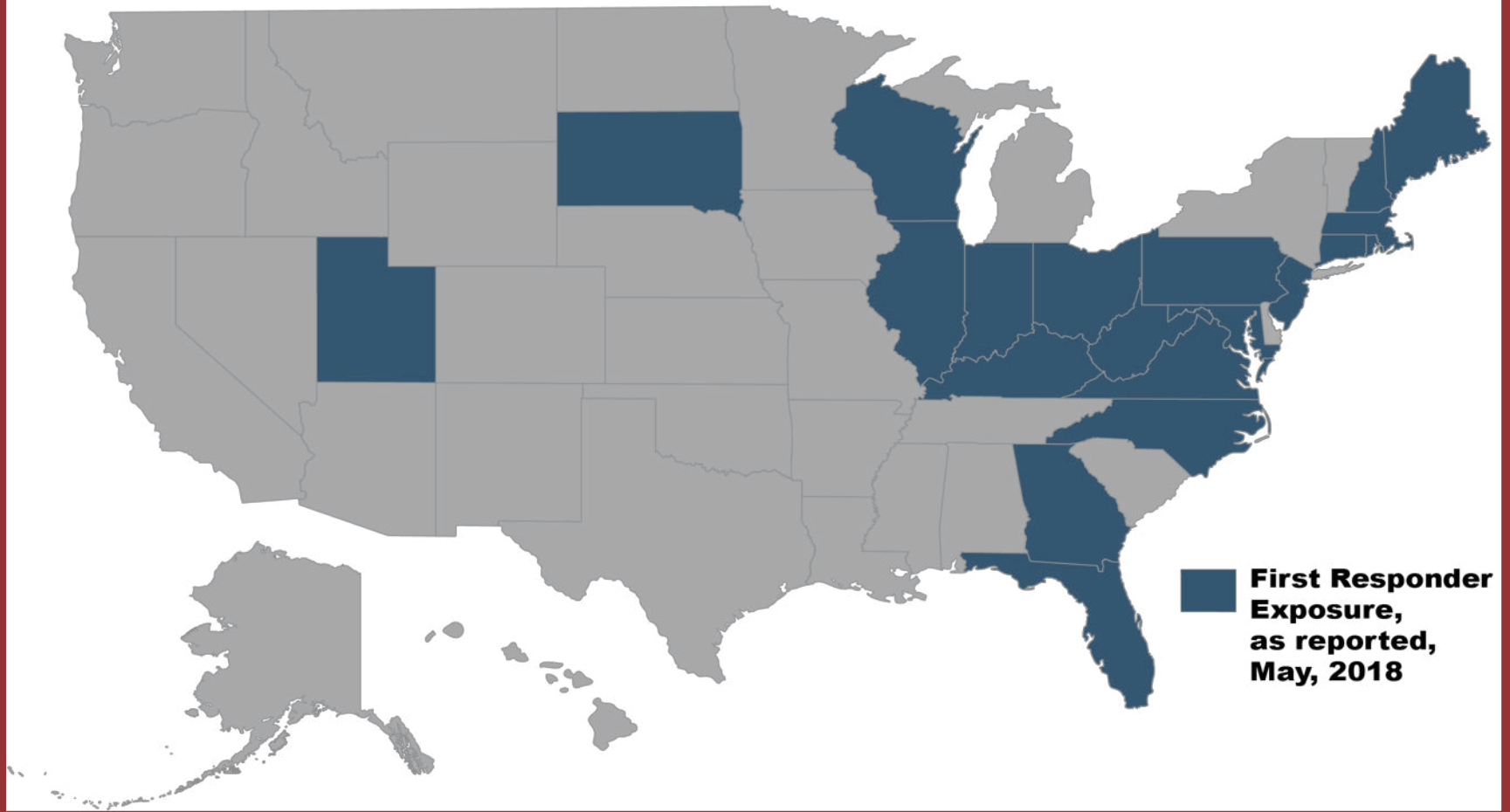


Law enforcement risk: officer exposure



Law enforcement risk: officer exposure

First Responder Fentanyl Exposures



How do we address this problem?

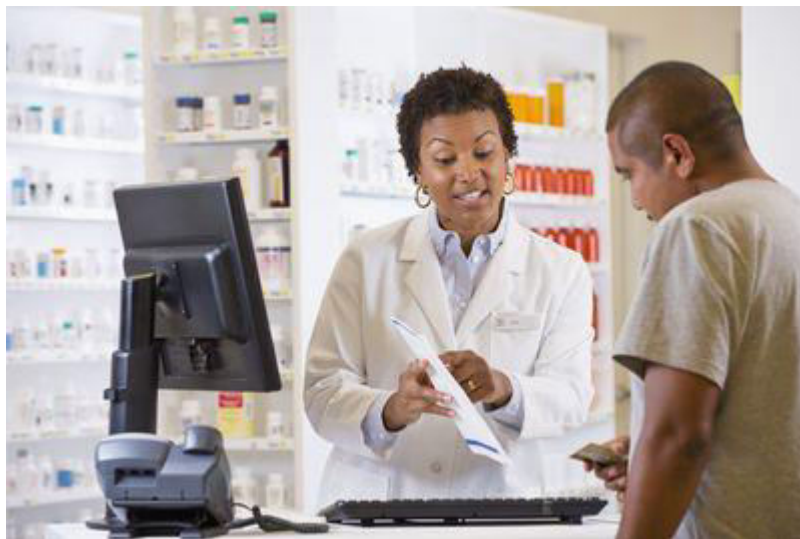
There are steps we can take to make the drug supply safer including resources for law enforcement, consumer education, and regulatory enhancement.

AND

There are steps we can avoid taking that would make the drug supply more dangerous.

What can we do?

We teach consumers that licensed pharmacies and pharmacists are the only safe sources of medication.



Friends and relatives,
even ones you trust,
are not as safe as a
licensed pharmacist.

 pharmacy®

What can we do?

Teach consumers how to save money safely so they don't buy off the black market.



SAFE SAVINGS TIP

GENERIC LIPITOR

(atorvastatin)



The Partnership for
SAFEMEDICINES.ORG®

47 of the 50 most frequently prescribed medications in the U.S. are available in cheaper generic form.

Americans **pay less** for most commonly prescribed generic medications than Canadians do.



The Partnership for
SAFEMEDICINES.org®
WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS

What can we do?

GoodRx Search drug prices

GoodRx Gold
Your Name Here

Pay Just \$8.54 with GoodRx Gold
Save even more on your family's prescriptions at **CVS, Kroger, Costco, Albertsons** and other nearby pharmacies.

Costco	\$18 est cash price	\$13.02 with free coupon
HealthWarehouse		\$13.50 purchase online
Target (CVS)	\$138 est cash price	\$18.00 with free coupon
Walmart		\$23.91 with free discount

MAPPING MEDICATION PRICES

In Raleigh, N.C., prices for the same drug—generic Cymbalta (duloxetine)—varied widely, even among stores that were just a few miles from each other.



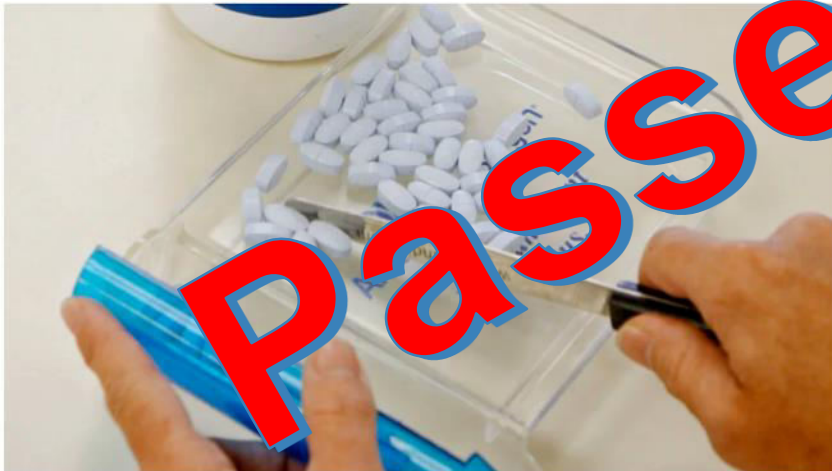
We always tell consumers to consolidate their prescriptions at a single pharmacy when recommending they shop around. Patients should have a single dispensing pharmacist, preferably a community pharmacist who knows the patient well.

What can we do?

Regulatory enhancement

boston.com NEWS WEATHER SPORTS CULTURE TRAVEL EVENTS CARS REAL ESTATE

Why your pharmacist can't tell you that \$20 prescription could cost only \$8



—Sue Ogrocki / AP, File

By ROBERT PEAR New York Times News Service, February 24, 2018

WASHINGTON — As consumers face rapidly rising drug costs, states across the country are moving to block "gag clauses" that prohibit pharmacists from telling customers that they could save money by paying cash for prescription

Support efforts to remove gag clauses that prevent pharmacists from helping patients save money.

What can we do?

Support the FDA's generic staffing levels through advocacy

FDA staffing is funded through a combination of user fees on generic drug makers and Congressional appropriations. When the FDA approves generics, especially multiple ones, prices go down and the market for counterfeits evaporates.



What can we do?

Support enhancement to border security through advocacy



Toured operations at #FDA JFK Airport mail facility. Just some of thousands of seized fake, controlled drug packages



9:33 AM - 25 Aug 2017



Sen. Rob Portman introduces the Synthetics Trafficking & Overdose Prevention (STOP) Act

More resources for package inspection at International Mail Facilities

Require electronic data on international mail to facilitate more efficient inspections

New legislative threat: Importation

- Allows non-FDA approved medication into the U.S.
- No increased CBP resources for package inspection
- Does not require prescription for foreign sellers to dispense any medication
- Contains no enforcement mechanism to punish foreign sellers of counterfeit or controlled substances
- Will create an enormous and nearly legitimate pathway for opioids and fentanyl analogues to enter the United States

Importation enforcement challenge



Chicago IMF



GAO



NYT – JFK IMF

Importation enforcement challenge

Unregulated Online Sellers

The screenshot shows a website for an online pharmacy. At the top, it displays currency (USD), language (EN), and contact information for the US and Europe. The main banner features a box of Cialis 30 pills x 21, priced at \$62.74 only, with an 'ORDER NOW' button. Below the banner, there are categories like Erectile Dysfunction, ED Sets, Allergies, Anti Fungal, Anti Viral, Antibiotics, Anxiety, Arthritis, and Asthma. The 'Bestsellers' section highlights three products: Viagra (\$0.35 per pill), Cialis (\$0.77 per pill), and Propecia (\$0.57 per pill). A red banner at the bottom states 'FREE PILLS FOR EVERY ORDER VIAGRA, CIALIS OR LEVITRA'. A 'FREE AIRMAIL DELIVERY' badge is also visible.

Package Inspection



Scott Gottlieb, M.D. [@SGottliebFDA](#)

Follow

Toured operations at [#FDA](#) JFK Airport mail facility. Just some of thousands of seized fake, controlled drug packages



9:33 AM - 25 Aug 2017

Every head of HHS and FDA for the last 18 years refused to certify the safety of drug importation.



Health & Human Services
(HHS) Secretary



"flaws and loopholes...make it impossible for me to demonstrate that it is safe and cost effective."
-Donna Shalala



"It's impossible for us to certify that these drugs are safe."
-Tommy G. Thompson



"The last thing we need is open borders for unsafe drugs in search of savings that can't be safely achieved. You can't improve competition and choice in our drug markets with gimmicks like these."
-Alex M. Azar II

Donna Shalala
(1993–2001)

Tommy G. Thompson
(2001–2005)

2003 MEDICARE
MODERNIZATION ACT

Michael O. Leavitt
(2005–2009)

Kathleen Sebelius
(2009–2014)

Sylvia Mathews Burwell
(2014–2017)

Alex M. Azar II
(2018–)

2000

2004

2008

2012

2016

2018

Mark Barr McClellan, M.D., Ph.D.
(2002–2004)

Margaret A. Hamburg, M.D.
(2009–2015)

Robert Califf, M.D.
(2016–2017)

Lester Mills Crawford, D.V.M., Ph.D.
(2005)

Scott Gottlieb, M.D.
(2017–)

Andrew C. von Eschenbach, M.D.
(2006–2009)



Commissioner of the
Food & Drug Administration



"Many U.S. consumers are being misled in the hopes of saving money by purchasing prescription drugs over the Internet from illegal pharmacies. Unfortunately, these drugs are often counterfeit, contaminated, unapproved products or contain an inconsistent amount of active ingredient. Taking these drugs can pose a danger to consumers."

-Margaret A. Hamburg, M.D.

It's not a **Republican** or **Democrat** issue.
It's a **safety** issue.

To see all of the HHS and FDA quotes go to <https://safedrug.gov/FDA-HHS>.

Opposition by four former FDA commissioners



March 16, 2017

To Members of Congress:

As former Commissioners of the U.S. Food and Drug Administration, we have been following with concern the recent measure to reduce the lower-cost but genuine not such a straightforward and risky approach—of harm patients and compromise the safety of our nation.

One of the FDA's most Americans are safe, and Cosmetic Act (FD&C) to protect consumers. direction of broadly su manufacturing practice shipment and storage, medications.

The American public are to and costs of prescri people with serious dis that enable affordable

However, routine impo importation of drugs p drugs purported to be imported from those c existing closed drug m tracked and certified b

Such a program would clothing, where consu consequences of fake undesirable effects, inc or counterfeit drugs. It highly successful syste importation scheme in

- Serious risks to FDA determine

- Any improved access and cost savings resulting from importation are likely to be minimal. Studies examining this issue have estimated that importation would likely have only a small, incremental effect on cost and access for drugs in the U.S. market; further, these small savings might not be passed on to patients, even if consumers are able to obtain a legitimate imported drug.

There are far better ways to improve access to safe and effective drugs. We believe Congress should consider other approaches to address problems with current drug pricing, and take steps to bring down drug costs and health care costs more generally. We all support drug payment reforms that align payments with results and development of improved guidance for industry to enable timely approval for complex generic drugs and "biosimilar" therapeutics.

The bipartisan Generic Drug User Fee Amendments Program, authorized by Congress in 2012, offers a successful model for such efforts. The program has promoted substitution of generic drugs, such that nearly 90% of prescriptions are now written for generic drugs that are safe, effective, and have yielded major savings for consumers. While we have some differing opinions about optimal approaches to the problem of high-priced drugs (such as government negotiation with manufacturers, or expanded use of competitive models of drug payment), we all strongly support attention to implementing effective solutions for drug costs and innovation.

We urge Congress and the many others concerned about the cost of drugs to deal directly with the issues driving the cost of medicines and not to place false hope in measures that will place patients who need treatment at risk and jeopardize public health.

Robert M. Califf, MD, MACC
Donald F. Fortin, MD Professor of
Cardiology
Duke University School of Medicine

Margaret A. Hamburg, MD
Foreign Secretary
National Academy of Medicine

Mark B. McClellan, MD, PhD
Margolis Professor and Director, Robert J.
Margolis, MD Center for Health Policy
Professor of Business, Medicine and Policy
Duke University

Andrew Von Eschenbach, MD

2017 Freeh report on importation

Key Findings:

- Increase counterfeits and illegal activity
- Worsen the opioid crisis
- Overburden law enforcement resources
- Endangers law enforcement



Law enforcement opposition



2017 - 07

NATIONAL SHERIFFS' ASSOCIATION OPPOSES DRUG IMPORTATION LEGISLATION WHICH JEOPARDIZES LAW ENFORCEMENT'S ABILITY TO PROTECT THE PUBLIC HEALTH AND ENDANGERS THE SAFETY OF LAW ENFORCEMENT AND OTHER FIRST RESPONDERS

WHEREAS, the number of drug overdose deaths in 2016 likely exceeded 59,000, representing the largest annual increase in the drug overdose death count ever recorded in the United States, and which are the consequence of an escalating public health crisis: opioid addiction; and,

WHEREAS, the Drug Enforcement Administration (DEA) reported in 2016 that the sudden arrival of wholesale amounts of counterfeit prescription drugs containing fentanyl (fueled by China-sourced fentanyl) into the United States via Canada and Mexico) will result in an increase in overdoses, deaths, and opiate-dependent individuals; and,

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JOIN NSA

HOME / NSA OPPOSES DRUG IMPORTATION LEGISLATION

NSA OPPOSES DRUG IMPORTATION LEGISLATION

Friday, July 28, 2017

Alexandria, VA -- At its Annual Conference this past June in Reno, NV, the National Sheriffs' Association (NSA) adopted a Resolution opposing drug importation legislation which jeopardizes law enforcement's ability to protect the public health and that endangers the safety of law enforcement and other first responders.

The Resolution, initiated by NSA's Drug Enforcement Committee, noted that the number of drug overdose deaths in 2016 represented the largest annual increase ever recorded in the United States, which is a consequence of the escalating opioid addiction crisis. Furthermore, the Drug Enforcement Administration (DEA) reports that the arrival of



2017 RESOLUTIONS

ADOPTED DECEMBER 2017

"[T]he IACP is gravely concerned about the dangers law enforcement personnel and their canine drug detecting partners are subject to each time they come into contact with fentanyl [...] the IACP opposes the passage of legislative drug importation proposals, which if implemented, would overextend and divert law enforcement resources and jeopardize law enforcement's ability to protect the public health, threaten the safety of our drug supply, and endanger the safety of law enforcement officers, their K-9 companions and first responders across America." - *International Association of Chiefs of Police (IACP), December 2017*

Law enforcement opposition



NATIONAL SHERIFFS' ASSOCIATION

JONATHAN F. THOMPSON
Executive Director and CEO

August 8, 2018

The Honorable Donald Trump
President of the United States
The White House
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear President Trump:

I write on behalf of more than 3,000 sheriffs across the country, expressing our concern with the Department of Justice's proposal to import prescription drugs from other countries.

This is not the first time that the National Sheriffs' Association has expressed concern with drug importation legislation which jeopardizes the health and endangers the safety of law enforcement officers.

And this concern of local Sheriff's perspective.

The three Key Findings of a 2017 Fresh Group International Solutions, LLC (June 2017), *Report on the Potential Impact of Drug Importation Proposals on U.S. Law Enforcement*, state that: (1) Drug importation proposals would worsen the opioid crisis by fueling criminal and drug trafficking organizations, in Canada and Mexico, and; (3) Already, the U.S. is unable to ensure a safe prescription drug supply.

Similarly, a March 16, 2017 report from the U.S. Department of Justice, *Drug Importation: A Review of the Potential for Abuse*, states that: (1) Serious risks to public health may be substantial, unsafe

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needed to oversee a major importation program; (4) The global drug supply will limit importation in access; and; (5) Any improved access and cost savings resulting from importation are likely to be minimal.²

Thus, on behalf of the Sheriffs of America, the National Sheriffs' Association respectfully requests that your Administration carefully weigh the potential harmful impact of drug importation on public safety and public health; and, while continuing to seek options "to lower drug prices and put American patients first," that the Administration take drug importation off the table of consideration.

Respectfully,

Jonathan F. Thompson
Executive Director and CEO

cc: The Honorable Alex Azar, Secretary, U.S. Department of Health and Human Services
Commissioner Scott Gottlieb, M.D., Food and Drug Administration
Ms. Kellyanne Conway, Counselor to the President
Acting Director Jim Carroll, Office of National Drug Control Policy

¹ HHS Secretary Azar Directs FDA to Establish Working Group on Drug Importation to Address Price Spikes, <https://www.hhs.gov/about/news/2018/07/19/hhs-secy-azar-directs-fda-establish-working-group-drug-importation-address-price-spikes.html>

² <https://www.sheriffs.org/files/default/files/Brochure%202017%20-%202018%20Drug%20Importation%20Letter%202017.pdf>

³ Fresh Group International Solutions, LLC (June 2017), *Report on the Potential Impact of Drug Importation Proposals on U.S. Law Enforcement*, https://storage.googleapis.com/fresh171820176605_Report%20on%20Counterfeit%20Drugs.pdf

⁴ https://healthpolicy.duke.edu/sites/default/files/ncmr/ncmr2017_03_18_commissioner_letter_fresh_signed.pdf

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August 2018

INDIANA SHERIFFS' ASSOCIATION OPPOSES LEGISLATION ON DRUG IMPORTATION

WHEREAS, the number opioid-related overdose deaths has drastically risen to an estimated 42,000 in 2016¹; and

WHEREAS, the number of opioid-related deaths from synthetic opioids was 19,413 in 2016², and the CDC has reported that the trend has extended into 2017, with more than 27,000 opioid-related overdose deaths involving synthetic opioids³; and

WHEREAS, the number of opioid-related overdoses in Indiana was 1,526 in 2016⁴; and

WHEREAS, there was an 80% increase in non-fatal opioid-related emergency room visits in Indiana from 2010-2015⁵; and

WHEREAS, the Drug Enforcement Administration (DEA) has seen a sharp increase in incidents of death and overdose from counterfeit prescription drugs containing fentanyl reaching the United States through Canada and Mexico⁶; and

WHEREAS, law enforcement throughout Indiana have seen fentanyl in counterfeit prescription opioid medications⁷, as well as in fake Xanax with deadly results⁸; and

WHEREAS, exposure to minimal amounts (as little as two milligrams) of fentanyl⁹ can endanger the health and safety of law enforcement officers, their K-9 companions and other first responders, as the DEA has repeatedly warned and publicized¹⁰ and



The Partnership for
SAFEMEDICINES.org[®]
WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS

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What can we do?

Provide enhanced authority and capabilities to the U.S. Food and Drug Administration (FDA) to more effectively enforce against counterfeit, misbranded or adulterated pharmaceuticals

- Provide FDA to destroy seized counterfeit
- Increase budgetary resources and FTEs
- Permanently schedule all fentanyl analogues
- Increase penalties and fines for counterfeit medicines production, distribution and sale



What can States do?

- Authorize and expand participation in federal taskforces
- Increase penalties and fines for counterfeit medicines production, distribution and sale
- Increase funding for county and local law enforcement to have rapid access to drug testing laboratories to get drug testing results for prosecutions



What can we do?

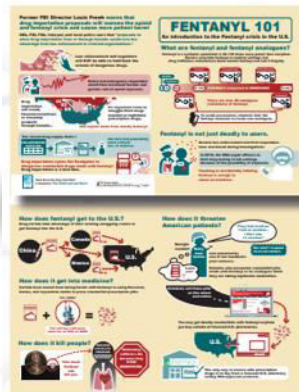
Materials to help educate consumers and healthcare professionals that interact with them.

Distribute our materials to consumers and pharmacists (we print them at cost for you!)

Re-share our materials on social media



Factpack
9" x 6" spiral-bound book—63 pages



Fentanyl 101
folded 11" x 14" pamphlet



"Don't Believe the Lies"
8.5" x 14" poster



5-Ways/6-Things Bookmark
3.5" x 8.5" 2-sided
informational bookmark



Bipartisan HHS/FDA
11" x 8.5" informational sheet



"Forty States and Counting"
Report
8.5" x 11" report—12 pages



Contact us to find out if we have materials about counterfeit drug investigations in your state:
editors@safemedicines.org



Print materials:
editors@safemedicines.org

Thank you